



Virginia
Regulatory
Town Hall

Final Regulation Agency Background Document

Agency Name:	Department of Health
VAC Chapter Number:	12 VAC 5-165-10 et seq.
Regulation Title:	Regulations for the Repacking of Crab Meat
Action Title:	Adopt new regulations to protect the safety of repacked crab meat.
Date:	March 27, 2000

Please refer to the Administrative Process Act (§ 9-6.14:9.1 *et seq.* of the *Code of Virginia*), Executive Order Twenty-Five (98), Executive Order Fifty-Eight (99) , and the *Virginia Register Form, Style and Procedure Manual* for more information and other materials required to be submitted in the final regulatory action package.

Summary

Please provide a brief summary of the new regulation, amendments to an existing regulation, or the regulation being repealed. There is no need to state each provision or amendment; instead give a summary of the regulatory action. If applicable, generally describe the existing regulation. Do not restate the regulation or the purpose and intent of the regulation in the summary. Rather, alert the reader to all substantive matters or changes contained in the proposed new regulation, amendments to an existing regulation, or the regulation being repealed. Please briefly and generally summarize any substantive changes made since the proposed action was published.

These regulations establish criteria by which the Virginia crab industry can safely repack both domestic and imported crab meat. Repacking involves the removal of crab meat picked and packed at another location and placing it in another container bearing the name of the local packer or distributor. Oversight of this activity is important because crab meat is a ready-to-eat, high hazard food. Pathogenic bacteria are easily inoculated into crab meat, where they can readily grow to harmful concentrations. Furthermore, large quantities of foreign crab meat is being imported into the U.S. from developing countries that have major public health problems such as cholera and hepatitis. This foreign product is being repacked without any labeling to indicate the country of origin, and if an outbreak occurs, public health officials will not be able to track where such crab meat has come from or where it has been shipped to. Substantive changes made since the proposed action involve a reduction in the amount of information about the foreign crab meat shipper and his product, and involve the addition of a penalty section and a prohibition against the blending of imported and domestic crab meat.

Changes Made Since the Proposed Stage

Please detail any changes, other than strictly editorial changes, made to the text of the proposed regulation since its publication. Please provide citations of the sections of the proposed regulation that have been altered since the proposed stage and a statement of the purpose of each change.

The following substantive changes were made in the proposed final version of the regulations:

1. The requirement for a repacker to obtain a letter from both the foreign crab meat packer and the foreign government or a recognized seafood authority was eliminated (12 VAC 5-165-120 in the originally proposed regulation).
2. The requirement that the repacker obtain records of product shipping temperatures was expanded to allow “other information sufficient to verify that the product was not temperature abused” (12 VAC 5-165-130 proposed, 12VAC 5-165-120 proposed final).
3. The requirement for the frequency of sampling and number of types of microorganisms to be tested for imported crab meat was reduced. Sampling was reduced from each shipment to the first two samples from each foreign shipper, and thence quarterly if the first two were acceptable. The number of types of microorganisms for testing was reduced from six types of tests to two (12 VAC 5-165-140 proposed, 12 VAC 5-165-130 proposed final).
4. A prohibition against the blending of foreign crab meat and domestic crab meat in the same container was added to the regulation (12 VAC 5-165-190 proposed final).
5. The requirement to keep records concerning blended domestic and foreign crab meat was eliminated (12 VAC 5-165-320 proposed) since a prohibition against blending was added to the proposed final regulations.
6. A new penalty section was added requiring the decertification of a dealer for 30 days if that plant is found to be repacking foreign crab meat into containers without the name of the foreign country of origin (12 VAC 5-165-330 proposed final).
7. Section 12 VAC 5-165-330 was added for emphasis since the Department does not prosecute for minor offenses of regulations. It restates the fact that operating without a Certificate of Operation is a Class 1 misdemeanor, as per Section 28.1-821 of the Code of Virginia.
8. Section 12 VAC 5-165-340 was also added for emphasis. It restates the fact that persons repacking foreign crab meat into a domestic container without the country of origin on the principal display panel is a Class 1 misdemeanor.

Statement of Final Agency Action

Please provide a statement of the final action taken by the agency: including the date the action was taken, the name of the agency taking the action, and the title of the regulation.

On February 4, 2000, the Virginia Board of Health adopted a final regulation entitled “Regulations for the Repacking of Crab Meat”.

Basis

Please identify the state and/or federal source of legal authority to promulgate the regulation. The discussion of this statutory authority should: 1) describe its scope and the extent to which it is mandatory or discretionary; and 2) include a brief statement relating the content of the statutory authority to the specific regulation. In addition, where applicable, please describe the extent to which proposed changes exceed federal minimum requirements. Full citations of legal authority and, if available, web site addresses for locating the text of the cited authority, shall be provided. If the final text differs from that of the proposed, please state that the Office of the Attorney General has certified that the agency has the statutory authority to promulgate the final regulation and that it comports with applicable state and/or federal law

Chapter 8 of Title 28.2 of the Code of Virginia (§28.2 -801 et. seq.) provides that the State Board of Health has the duty to protect the public health and to ensure that all shellfish, crustacea (crab meat) and finfish destined for public consumption be safe and wholesome. Section 28.2 -801 provides that the State Board of Health may promulgate regulations necessary to carry out the provisions of the chapter and that the State Health Commissioner (Commissioner) shall enforce those provisions. Section 28.2 -803 authorizes the Commissioner to “conduct an examination or analysis of crustacea, finfish and shellfish, whether on the planting grounds, in an establishment, or in any other place in this Commonwealth, from which the products are to be taken or sold for food purposes.” This section requires that the Commissioner examine the establishments in which crustacea are handled “and the sanitary conditions surrounding the establishment.” Section 28.2 -806 authorizes the Commissioner to establish and change standards, which control the marketing of crustacea from a health standpoint.

Purpose

Please provide a statement explaining the need for the new or amended regulation. This statement must include the rationale or justification of the final regulatory action and detail the specific reasons it is essential to protect the health, safety or welfare of citizens. A statement of a general nature is not acceptable, particular rationales must be explicitly discussed. Please include a discussion of the goals of the proposal and the problems the proposal is intended to solve.

The purpose of these regulations is to establish criteria by which crab processors can safely repack both domestic and imported crab meat. The Department has a standard forbidding the repacking of crab meat, but this standard does not carry the force of law. While the Commissioner of Health has been issuing variances to this standard, the Department has become aware that unscrupulous packers may be ignoring this standard, and there is little that the Department can do to stop the practice.

The repacking of crab meat poses significant public health concerns, since crab meat is a good growth medium for pathogenic bacteria, and it is often eaten without further cooking.

When crab meat is repacked, certain procedures must be followed that will prevent contamination of the product and prevent the growth of pathogenic bacteria. Furthermore, foreign crab meat is being widely imported into the US from developing countries where such diseases as hepatitis and cholera are common and are easily spread via the contamination of food. This foreign crab meat is being repacked in domestic containers without any indication of the country from which the meat originates. Unless the Department can control the situation, in the event of an outbreak due to foreign crab meat, there would likely be no way to trace where the meat came from nor where it was shipped. Thus the Department needs these regulations.

Substance

Please identify and explain the new substantive provisions, the substantive changes to existing sections, or both where appropriate. Please note that a more detailed discussion is required under the statement of the regulatory action's detail.

These new regulations will allow a crab processor to be certified to repack both domestic and imported crab meat. Currently the Department does not have a regulation concerning this practice, though it does have an unenforceable standard forbidding the practice.

Repackers shall have and maintain an approved Hazard Analysis Critical Control Point (HACCP) plan. A HACCP plan is a procedure that the repacker develops and follows to insure that he produces a safe food product. The repacker conducts a hazard analysis to determine whether his repacking process entails any steps that could cause the food to be hazardous, and then determines the control points in his process that are critical to protecting the crab meat. The repacker is responsible for monitoring these critical control points and for maintaining records to show that proper procedures have been followed. For example, the repacker would likely indicate that temperature control is critical, and would monitor the temperature of the crab meat coolers for either proper temperature control or the presence of ice on the crab meat containers. These HACCP plans are currently required by the US Food and Drug Administration, and this regulation would not exceed the federal requirement.

If repacked crab meat must be recalled from markets, normally the entire production lot would have to be recalled, unless the repacker can use another reliable mechanism for distinguishing potentially hazardous product from safe product. This will be a new regulation but not a new practice, because whenever product is found to be unsafe and must be recalled, an attempt is made to recall all product that was produced during the time period of concern. For example, occasionally pasteurized crab meat containers are found to be defective, and when this happens, the entire production lot of meat processed is recalled or embargoed and checked to be sure there is no threat of botulism poisoning.

Crab meat for repacking will have to come from a facility that has been inspected by a public health authority. All crab meat producing states in the US have an inspection and certification program for crab meat packers, so this would impose no difficulty for finding sources of domestic crab meat. The Department believes that crab meat from foreign countries for repacking should also originate from a facility inspected by the foreign country's public health authority.

The following new regulations will apply when imported crab meat is used:

- 1.) The repacker will provide a record of international transport temperature conditions or other information sufficient to insure that the product was not temperature abused. Temperature abuse during international transport is a major concern since pathogenic bacteria may grow out if the meat is not properly refrigerated.
- 2.) The repacker shall take a minimum of five samples from each of the first two shipments from a particular dealer and analyze them for decomposition and certain microbiological contaminants. If any sample is found to contravene a guideline, the repacker shall contact the Department for guidance concerning the lot. If results of these samples are acceptable, then the sampling can be reduced to every three months.
- 3.) If pasteurized crab meat is used, the repacker will obtain a letter from the foreign producer stating that the meat was pasteurized to the degree conducted in Virginia. Crab meat pasteurized along the US East and Gulf Coasts are all processed in a manner to provide essentially the same amount of public health protection. The Department believes that crab meat pasteurized in a foreign country should receive the same minimal amount of thermal processing.
- 4.) The crab meat will be pasteurized either in the foreign country or by the repacker. Pasteurization is the one process that will ensure that such disease causing organisms as hepatitis and cholera are not alive in crab meat imported from developing countries.
- 5.) All containers of repacked meat shall be labeled with the country of origin.

All crab meat repacking will be conducted separately in time or space from other operations, and the tables will be cleaned and sanitized prior to and after processing. This requirement is proposed because crab meat, when brought into a plant, may contain pathogenic organisms that were not present in the plant to begin with. By cleaning up before and after repacking, one can be sure that no pathogens from one lot are transferred to another lot, and if an outbreak should be traced to a specific lot, then only that lot would need to be recalled.

No portion of the crab meat will exceed 50 degrees F during repacking. Most pathogenic organisms of concern will not substantially grow at or below 50 degrees F.

Containers of repacked crab meat will be labeled with a lot number. The addition of a lot number to the container would allow public health officials to differentiate crab meat containers of concern during an outbreak from those not of concern.

Issues

Please provide a statement identifying the issues associated with the final regulatory action. The term "issues" means: 1) the advantages and disadvantages to the public of implementing the new provisions; 2) the advantages and disadvantages to the agency or the Commonwealth; and 3) other pertinent matters of interest to the regulated community, government officials, and the public. If there are no disadvantages to the public or the Commonwealth, please include a sentence to that effect.

The public would enjoy two primary benefits if these regulations were adopted. The public could continue to expect to receive a safe product, whether it came from a foreign country or not. When purchasing crab meat, the consumer would be much more likely to know whether the meat originated from a foreign country or not.

If these regulations were adopted, the Virginia crab meat industry would enjoy the ability to compete on a "level playing field." Currently, some unscrupulous crab meat dealers are repacking inexpensive foreign crab meat and are representing it as domestic crab meat when they sell it at a lower price than the true domestic product. This places the domestic crab meat packer at an economic disadvantage.

There are no disadvantages to the public.

The disadvantages to the honest crab meat repackers are minor, since they have been following most of these practices for the repacking of domestic crab meat for years. The disadvantages for the repackers of imported crab meat are that they will have increased record keeping responsibilities and minimal increased costs.

Public Comment

Please summarize all public comment received during the public comment period and provide the agency response. If no public comment was received, please include a statement indicating that fact.

1.) Concern: Verification of HACCP for imported crab meat (originally proposed 12VAC5-165-120).

Public Concern Raised:

The requirement for a repacker to obtain a letter from both the foreign crab meat packer and the foreign government, or a recognized seafood safety authority is unnecessary and an extra burden on industry. The industry argued that the US Food and Drug Administration (FDA) already requires that the original importer verify that the crab meat has been produced under a HACCP plan equivalent to US standards. As such, requiring the Virginia repacker to seek out additional verification is unnecessary.

VDH Response:

VDH agrees with this point and that requirement has been eliminated from the proposed final regulations.

2.) Concern: Verification of shipping temperatures for imported crab meat (proposed final 12 VAC 5- 165-120).

Public Concern Raised

The requirement that the repacker obtain records of product temperatures during shipping is overly difficult to achieve. Shipping companies do not supply records of shipping temperatures, instead they issue a letter of guarantee that products will be kept to a certain temperature. If those temperatures are not maintained, the shipping company issues a notice of failure. The industry requested that other means of insuring proper shipping temperatures be allowed.

VDH Response:

VDH agrees with this point. The maintenance of proper temperature control during international shipping is apparently well controlled, and the agency will accept a letter of guarantee from the shipping company. The regulation has been modified to allow “other information sufficient to verify that the product was not temperature abused.”

3.) Concern: Sampling and analysis requirements for imported crab meat (proposed final 12 VAC 5-165-130).

Public Concern Raised

That the sampling and analysis requirements are excessive.

VDH Response

VDH agrees with this point. When these regulations were first developed, FDA had not promulgated its HACCP regulation. HACCP is now in place and addresses many of the food production concerns in a different manner than by extensive product testing. Under HACCP, testing is used as a verification procedure to validate records keeping, and thus less sampling is needed. Therefore, the frequency of microbiological testing was reduced, requiring the first two shipments from a particular source be sampled. If all samples from both initial shipments meet the specified action levels, then the sampling interval may be reduced to quarterly sampling. Samples will be analyzed microbiologically for fecal coliforms and aerobic plate count.

Properly conducted organoleptic sensing is a powerful tool for detecting decomposition in crab meat. Since such testing can be done by the Virginia plant at little or no extra expense, the requirement for this testing of every shipment was left in the proposed final regulations.

4.) Concern: Blending of domestic and foreign crab meat (proposed final 12 VAC 5-165-190)

Public Concern Raised

There was a very strong outcry from the crab meat industry against allowing the blending of foreign crab meat with domestic crab meat during the repacking process. The Virginia Seafood Council polled all the Virginia crab meat dealers (a total of 35), and 15 (43%) responded. Fourteen of the fifteen dealers were opposed to such blending. In addition, VDH received a letter from one Virginia waterman and the Maryland Chesapeake Bay Seafood Industries Association in opposition to blending. The near unanimous opinion is that this blending would lead to the downfall of the domestic crab meat industry. The reasons for their concern are that the blended meat would be cheaper than domestic meat, and would be confused with and degrade the good name of blue crab meat. Also, they were concerned that blending would make it even harder to detect improperly labeled foreign meat.

VDH Response

VDH revised the regulation in accordance with the wishes of the vast majority of the crab meat industry, thus forbidding the blending of domestic and foreign crab meat. VDH perceives this issue as being primarily an economic concern, with some public health implications. VDH believes that crab meat can be blended in a manner that will not pose an unacceptable public health risk; however, in the event of an outbreak, tracing back to the source of the problem would be complicated by a product blended from one or more original sources. Unless meticulous records were kept, it might not be possible to identify the source of the contamination.

5.) Concern: Temperature of crab meat during repacking (proposed final 12 VAC 5-165-200).

Public Concern Raised

A request was made to allow crab meat to exceed 50 degrees F for not more than one hour during the repacking operation.

VDH Response

This request was deemed inappropriate to good public health practices. This crab meat may have already been picked under conditions where it was out of temperature control for the maximum amount of time allowed in the FDA Fish and Fisheries Products Hazards & Control Guide. As such, any more time out of temperature control would be deemed inappropriate and excessively risky.

6.) Concern: Penalties (proposed final Part III, Article 4)

Public Concern Raised

One of the prime concerns of the industry is the difficulty that VDH will have in trying to enforce these proposed regulations. The industry believes that having regulations that allow repacking will serve to enhance covert repacking unless there is a significant deterrent.

VDH Response

VDH concurs with much of this assessment. The shellfish program has never faced the type of situation posed by inappropriate labeling. The economic incentive to mislabel foreign crab meat and sell it at inflated domestic prices is so strong that no state agency could adequately attain compliance without a significant deterrent.

VDH has added a new penalty article. Regulation 12VAC 5-165-320 will require the decertification of a dealer for 30 days if that plant is found to be repacking foreign crab meat into containers without the name of the foreign country of origin. Regulations 12 VAC 5-165-330 and 12 VAC 5-165-340 restate (for emphasis) the fact that failure to abide by the regulations is a Class 1 misdemeanor as specified in the Code of Virginia, §32.11-27.

7.) Concern: The Repacking of Foreign Crab Meat

Public Concern Raised

Some of the Virginia crab meat industry is strongly opposed to the entire concept of the repacking of foreign crab meat. However the industry is divided on this concept. When the Virginia Seafood Council polled the Virginia crab meat industry members, they found four of eleven members to be in favor of the repacking regulations as generally written.

The industry concerns are based in economics, and are not a public health issue. These industry members want VDH to forbid the repacking of foreign crab meat, because they believe the repacking of foreign crab meat will put the domestic industry out of business.

VDH Response

Since this is an economic issue, and not a public health issue, and since the industry appears to be divided in its opinion, VDH believes that it cannot forbid the repacking of foreign crab meat. VDH believes that foreign crab meat can be safely repacked under the conditions specified in these proposed regulations, and that VDH is restricted to considering only the public health issues in this case.

VDH wishes to emphasize its conviction that regulations to control the repacking of crab meat, though somewhat controversial, are needed.

Detail of Changes

Please detail any changes, other than strictly editorial changes, that are being proposed. Please detail new substantive provisions, all substantive changes to existing sections, or both where appropriate. This statement should provide a section-by-section description - or crosswalk - of changes implemented by the proposed regulatory action. Include citations to the specific sections of an existing regulation being amended and explain the consequences of the changes.

Since these are new regulations, there are no changes to existing regulations for comparison. However, these regulations do change current regulatory law. The regulations will provide the Department of Health with the authority to require HACCP plans for crab meat repackers. While this is already federal law, the Department agrees with this well established approach to

processing plant sanitation. Section 12 VAC 5-165-80 provides the Department with the ability to enforce these requirements, and aids the Virginia industry by essentially giving the State primacy in this area. The seafood industry generally prefers for state agencies to be in charge of direct regulation rather than federal agencies, specifically the U.S. Food and Drug Administration in this case.

Part II of the proposed final regulations insures that repackers of crab meat will use crab meat that comes from sanitary sources, and that the meat will not contain pathogenic organisms.

Part III, Article 1 of the proposed final regulations insures that pathogens will not be introduced into the crab meat during the processing operation. Section 12 VAC 5-165-230 requires all imported crab meat to be pasteurized to insure that disease organisms that are much more prevalent in developing countries and which may be present in crab meat are killed.

Part III, Articles 2 and 3 require certain labeling and records keeping, so that in the event of an outbreak, the original product can be identified. This helps contain outbreaks to a minimal size.

Part III, Article 4 contains a substantially new penalty section, 12 VAC 5-165-320. This section would require a 30-day decertification period for a facility found to be packing foreign crab meat into a container that did not have the country of origin on the label. The crab meat industry was insistent that a substantial penalty be included in these regulations so that the Department could prevent cheating on the part of dishonest repackers.

Family Impact Statement

Please provide an analysis of the regulatory action that assesses the impact on the institution of the family and family stability including the extent to which the regulatory action will: 1) strengthen or erode the authority and rights of parents in the education, nurturing, and supervision of their children; 2) encourage or discourage economic self-sufficiency, self-pride, and the assumption of responsibility for oneself, one's spouse, and one's children and/or elderly parents; 3) strengthen or erode the marital commitment; and 4) increase or decrease disposable family income.

These proposed regulations will have no effect on the authority and rights of parents in the education, nurturing and supervision of their children.

These proposed regulations may help maintain the economic self-sufficiency and self-pride of Virginia watermen and of the owners of many Virginia crab meat packing facilities by preventing the sale of foreign crab meat posed as being domestic product, and thus protecting the value of Virginia's premium product.

These proposed regulations will have no effect on the assumption of responsibility for oneself, one's spouse, and one's children and/or elderly parents.

These proposed regulations will have no effect on the marital commitment.

These proposed regulations will not directly increase or decrease disposable family income. However, they may indirectly prevent the decrease of disposable family income for many owners of crab meat packing facilities and for watermen by preventing the demise of their livelihood. Most Virginia packers believe that the unregulated repacking of foreign crab meat would destroy their business, and would greatly affect the watermen that supply their establishments with local crabs.